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P.O. BOX 980
VALLEY FORGE, PA 19482

EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,840	CARDONA IGLESIAS ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-60* is/are pending in the application.

4a) Of the above claim(s) *13-19,21-27,35-37 and 44-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,28-34,38-43 and 47-60* is/are rejected.

7)☒ Claim(s) *20, 28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/1/2009;6/4/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

Applicants' response of June 4, 2009, to the non-final action dated March 11, 2009, has been entered. No claims were amended, cancelled or newly added. Currently, claims 13-60 are pending in the Application.

Claim Claims 13-19, 21-27, 35-37 and 44-46 stand withdrawn from further consideration, with traverse, pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01. The claims have been examined commensurate in scope of the invention, i.e. a lyophilized immunotherapeutic agent and a pharmaceutical agent that contain cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain of cells and with the elected species of H37Rv as the species of MTB-C strain, octylphenol ethoxylate having 7-8 mol of ethylene oxide as the species of non-ionic surfactant and phosphatidylcholine as the species of liposome auxiliary lipid.

Claims 20, 28-34, 38-43 and 47-60 are under current examination.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on May 1, 2009 contains foreign patent document ES 2231037, not in the English language. The IDS indicates the foreign document as corresponding to the instant patent application publication No. U.S. 2007/0269501, that has been separately considered, and indicated as such on Applicants' IDS form.

New Claim Objections

Claims 20, 28 and 29 and are newly objected for requiring the particulars of withdrawn claims. Claims 20 and 29 requires particulars of withdrawn claim 13. Claim 28 requires the particulars of withdrawn claim 21. The objection may be obviated by amending the claims to recite the particulars of the withdrawn claims.

Response & Maintained Claim Rejections - 35 USC § 103

Claims 20, 28, 29, 38, and 47-55 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (U.S. Patent Application Publication No.: 2002/0094336; filed Feb. 20, 2001; of record), in view of Chatuverdi et al. (Vaccine 17:2882-2887; 1999). The rejection set forth on pp. 73-5 of the previous Office action dated March 11, 2009 is maintained for reasons of record.

The rejection is reiterated for the record as follows:

The claims embrace an immunotherapeutic agent containing cell wall fragments from a virulent *Mycobacterium tuberculosis* H37Rv strain of cells and a pharmaceutical composition comprising the same.

Applicants have acknowledged that the immunotherapeutic agent in claim 20 is claimed as product by process claim, that reads on a homogenate of cells comprising non-fragmented cells and cell wall fragments. As non-fragmented cells include virulent H37Rv, such would not be considered immunotherapeutic. Claim 20 has therefore been examined to the extent that that the agent encompasses cell wall fragments of the H37Rv strain.

MPEP 2112.01 states: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)."

MPEP 2113 further states: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Andersen et al. describe immunologically active peptide fragments of *M. tuberculosis* that may be used as compositions such as vaccines (Title and Abstract). The authors state that

recombinant polypeptides may be isolated from whole bacteria of the tuberculosis complex for from lysates or fractions thereof, e.g. cell wall containing fractions (paragraph [0078], p. 9). Andersen et al. further state that in order to find new *M. tuberculosis* specific antigens for a new vaccine against TB, various ORF regions of *M. tuberculosis* H37Rv has been analyzed, as these regions are deleted from known BCG strains (paragraph [0175], p. 17. Andersen et al. further state that the vaccine comprising the immunogenic polypeptides may be prepared as a pharmaceutically acceptable ingredient containing auxiliary substances such as emulsifying and buffering agents (paragraph [0097], p. 11). Preparation of proteins in PBS buffer is described in Example 3, paragraph [0214], limitation of claim 52).

While Andersen et al. do not describe the preparation of Mycobacterial cell wall fragments, such was known in the prior art.

Chaturvedi et al. describe the preparation of protective antigens from the cell wall of *Mycobacterium habana* (Title and Abstract), by sonication, differential centrifugation, phase separation using Triton X-114, centrifugation, backwashing in buffer having a neutral pH, and recovery of protein fractions by precipitation and lyophilization (sections 2.1 and 2.3 p. 2883; limitation of claims 28 and 51). The authors present results from cell wall fraction vaccination against *M. tuberculosis* H37Rv, and state that the strain is a good choice as a candidate vaccine for tuberculosis (first column, p. 2887).

The teachings of Andersen et al. and Chaturvedi et al. are directed to the production of Mycobacterial protein vaccines. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art, to combine their respective teachings and to isolate cell wall fragments from the H37Rv strain for producing a vaccine composition, as instantly claimed, with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would have been motivated to isolate cell wall fragments and formulate the same as a pharmaceutical vaccine composition, because Anderson et al. specifically teach pharmaceutical vaccine compositions of H37Rv strain proteins.

Response to Arguments:

Applicants disagree, and with reference to MPEP 2113 argue that he Office has considered the claimed immunotherapeutic agent as only comprising cell wall fragments from a virulent *Mycobacterium tuberculosis* H37Rv strain. However, the immunotherapeutic agent of the instant invention is obtainable by a process comprising the steps of a) culturing the cells of a virulent *Mycobacterium tuberculosis* - complex (MTB-C) strain for a period of at least three weeks and b) homogenizing the cells in the presence of a non-ionic surfactant to produce a homogenate comprising non-fragmented cells, cell wall fragments, and solubilized cell compounds; and a person having ordinary skill in the art, the steps and conditions of the process (i.e., the culture period, and the fact that the homogenization is carried out in the presence of a non-ionic surfactant) will impart distinctive structural characteristics to the final product (e.g., the non-ionic surfactant is expected to form micelles and solubilize part of the cell components including some components of the cell wall and some antigens). Applicant's arguments have been fully considered, but are not found persuasive.

In response, it should be noted that the previous Office action clearly indicated that the claims have been examined commensurate in scope of the invention, i.e. a lyophilized immunotherapeutic agent and a pharmaceutical agent that contain cell wall fragments from a virulent *Mycobacterium tuberculosis*-complex (MTB-C) strain. The previous Office action further indicated that "the immunotherapeutic agent in claim 20 is claimed as a product by process claim, that reads on a homogenate of cells comprising non-fragmented cells and cell wall fragments. As non-fragmented cells include virulent H37Rv, such would not be considered immunotherapeutic. Claim 20 has therefore been examined to the extent that that the agent encompasses cell wall fragments of the H37Rv strain."

It should further be noted that the method steps recited in withdrawn claim 13 do not result in a lyophilized immunotherapeutic agent, elected by Applicants. Such is further evidenced by Applicants' own specification, exemplifying the production of the immunotherapeutic agent by the steps of homogenization in the presence of Triton X—114, centrifugation so as to remove non-fragmented cells, washing and centrifugation to remove and discard soluble proteins in the supernatant, and lyophilization of only the remaining cell wall fragments (Example 1, pp. 6-7). The same process that includes the elimination of virulent cells is set forth in instant claim 53,

that Applicants appear to have ignored. As previously indicated, non-fragmented cells include virulent H37Rv, that if administered, would likely lead to tuberculosis in the recipient subject, and thus cannot be considered an immunotherapeutic. Such is further contrary to Applicants own specification. Further, Applicants have stated on the record that the specification and instant claim 53 indicate that the non-ionic surfactant is expected to form micelles and solubilize part of the cell components including some components of the cell wall and some antigens. However, such solubilized fraction is removed or discarded according to both the instant specification and instant claim 53. Thus, it is only the non-solubilized cell wall fraction that is the immunotherapeutic agent.

With regard to the culture of the mycobacterium for at least three weeks, such is not accorded patentable weight, because culturing time is within the purview of a person of ordinary skill in the art and constitutes routine optimization to obtain a desired yield of mycobacteria, that include scale-up culture of slow growing bacteria. As indicated in MPEP 2144.05, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Routine optimization is not inventive, and no evidence has been presented here to suggest that the culture period necessarily results in significant structural differences. Such is further evident from the open-ended range claimed.

With regard to homogenization in the presence of a non-ionic surfactant, Chaturvedi et al. describe the preparation of protective antigens from the cell wall of *Mycobacterium habana* (Title and Abstract), by sonication, differential centrifugation and phase separation using Triton X-114, followed by further treatment of both the aqueous and detergent phases with Triton X-114. It should be further noted that Triton X-114 is the elected species of non-ionic surfactant under examination. Thus, there is no evidence that the lyophilized cell wall fraction instantly claimed would be structurally or functionally distinct from that taught and suggested by the prior art.

Applicants argue that the immunotherapeutic agent of the invention has been found to be suitable for treating tuberculosis; and it has been found unexpectedly to have a synergistic activity when given as a combined treatment with drugs (e.g., isoniazid or rifampicin). In

response, it is noted that Applicants' allegation of unexpected results is not commensurate in scope with the instant claims, as the claims do not require a combination with any other drug.

Applicants argue that Andersen et al. immunologically active polypeptide fragments which comprise a sequence derived from more than 30 antigens and only one was isolated from the cell wall fraction of H37Rv described by Sorensen et al. that differs from that of the instant invention. Such is not found persuasive, because Applicants have ignored the teachings of Chaturvedi et al. with respect to using Triton X-114 non-ionic surfactant in the isolation process. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants again attack the references individually, arguing that the Mycobacterium strain used by Chaturvedi et al. is *Mycobacterium habana* and not the virulent H37Rv strain. Such is not found persuasive, because Chaturvedi et al. present results from cell wall fraction vaccination against *M. tuberculosis* H37Rv, and state that the strain is a good choice as a candidate vaccine for tuberculosis (first column, p. 2887). Further, Anderson et al. specifically teach pharmaceutical vaccine compositions of H37Rv strain proteins.

Applicants argue that in Chaturvedi, the preparation of the cell wall fraction does not include a phase separation using Triton X-114, as suggested by the Office Action. The phase separation using Triton X-114 is performed instead over the membrane fraction of *Mycobacterium habana* (sections 2.1 and 2.3 p. 2883); and that the cell wall fraction is prepared merely by sonication and differential centrifugation, citing an earlier publication by Chaturvedi.

In response, it is noted that Applicants' method of homogenizing the cells in the presence of non-ionic detergent necessarily includes treatment of the cell membrane fraction with Triton X-114 as described by Chaturvedi et al. Further, as indicated above, Applicants' specification and instant claim 53 indicate that all soluble fractions are separated from the cell wall fraction and discarded (that would include all proteins solubilized by the non-ionic surfactant), and only the insoluble cell wall fraction is used as an immunotherapeutic.

Thus, the rejection is maintained for reasons of record and the foregoing commentary.

Claims 28-33, 38-42, 47, 54 and 56-59 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (U.S. Patent Application Publication No.: 2002/0094336; filed Feb. 20, 2001; of record), in view of Chatuverdi et al. (Vaccine 17:2882-2887; 1999), as applied to claims 20, 28, 29, 38, and 47-55 above, and further in view of Unger et al. (U.S. Patent No.: 6,443,898; filed June 7, 1995). The rejection set forth on pp. 5-6 of the previous Office action dated March 11, 2009 is maintained for reasons of record.

The rejection has been reiterated for the record as follows:

The claims embrace an immunotherapeutic agent containing cell wall fragments from a virulent *Mycobacterium tuberculosis* H37Rv strain of cells and a pharmaceutical composition comprising the same in the form or liposomes.

Andersen et al. describe immunologically active peptide fragments of *M. tuberculosis* that may be used as compositions such as vaccines (Title and Abstract). Andersen et al. further state that in order to find new *M. tuberculosis* specific antigens for a new vaccine against TB, various ORF regions of *M. tuberculosis* H37Rv has been analyzed, as these regions are deleted from known BCG strains (paragraph [0175], p. 17. Andersen et al. further state that the vaccine comprising the immunogenic polypeptides may be prepared as a pharmaceutically acceptable ingredient containing auxiliary substances such as emulsifying and buffering agents (paragraph [0097], p. 11).

Chaturvedi et al. describe the preparation of protective antigens from the cell wall of *Mycobacterium habana* (Title and Abstract), by sonication, differential centrifugation, phase separation using Triton X-114, centrifugation, backwashing in buffer having a neutral pH, and recovery of protein fractions by precipitation and lyophilization (sections 2.1 and 2.3 p. 2883; limitation of claims 28 and 51). The authors present results from cell wall fraction vaccination against *M. tuberculosis* H37Rv, and state that the strain is a good choice as a candidate vaccine for tuberculosis (first column, p. 2887).

While Chaturvedi et al. do not describe the preparation of their Mycobacterial cell wall fragments a part of a liposome, such was known in the prior art.

Unger et al. describe therapeutic delivery systems comprising liposomes having encapsulated therein drugs (Abstract). Unger et al further describe various suitable therapeutics that include bacterial vaccines, microbial cell wall components and subunits of Mycobacteria (paragraph 91). Unger et al. state that dipalmitoyl-phosphatidylcholine may be included in the emulsification process to produce the liposomes (paragraph 11, 52 and 68), further disclosing phospholipid liposomes having a cholesterol coating (paragraphs 12, 13 and 79). Combinations of phosphatidylcholine and cholesterol are disclosed in paragraph 211.

The teachings of Andersen et al. Chaturvedi et al. and Unger et al. are directed to the production of Mycobacterial protein vaccines. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art, to combine their respective teachings and to produce cell wall fragments from the H37Rv strain encapsidated in liposomes as a vaccine composition, as instantly claimed, with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would have been motivated to utilize the cell wall components as a liposomal pharmaceutical vaccine composition, because Unger et al. specifically teach the same.

Response to Arguments:

Applicants disagree with the rejection, repeating substantially the same arguments summarized above. Applicants' arguments have been fully considered, but are not found persuasive. Applicants are directed to the response set forth above. Thus, the rejection is maintained.

Claims 28, 38, 39, 43, 47, 54 and 56-60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (U.S. Patent Application Publication No.: 2002/0094336; filed Feb. 20, 2001; of record), in view of Chatuverdi et al. (Vaccine 17:2882-2887; 1999), and further in view of Unger et al. (U.S. Patent No.: 6,443,898; filed June 7, 1995) as applied to claims 28-33, 38-42, 47, 54 and 56-59 above, and Parikh I. (U.S. Patent No.: 5,785,975; Jul. 28, 1998).

The rejection set forth on pp. 6-8 of the previous Office action dated March 11, 2009 is maintained for reasons of record.

The rejection has been reiterated for the record as follows:

The claims embrace an immunotherapeutic agent containing cell wall fragments from a virulent *Mycobacterium tuberculosis* H37Rv strain of cells and a pharmaceutical composition comprising the same in the form or liposomes, further comprising vitamin E.

Andersen et al. describe immunologically active peptide fragments of *M. tuberculosis* that may be used as compositions such as vaccines (Title and Abstract). Andersen et al. further state that in order to find new *M. tuberculosis* specific antigens for a new vaccine against TB, various ORF regions of *M. tuberculosis* H37Rv has been analyzed, as these regions are deleted from known BCG strains (paragraph [0175], p. 17.

Chaturvedi et al. describe the preparation of protective antigens from the cell wall of *Mycobacterium habana* (Title and Abstract), by sonication, differential centrifugation, phase separation using Triton X-114, centrifugation, backwashing in buffer having a neutral pH, and recovery of protein fractions by precipitation and lyophilization (sections 2.1 and 2.3 p. 2883; limitation of claims 28 and 51).

Unger et al. describe therapeutic delivery systems comprising liposomes having encapsulated therein drugs (Abstract). Unger et al further describe various suitable therapeutics that include bacterial vaccines, microbial cell wall components and subunits of Mycobacteria (paragraph 91).

While Unger et al. do not describe their liposome delivery system as comprising vitamin E, such was known in the prior art.

Parikh describes phospholipid adjuvant compositions and vaccine formulations (Abstract), stating that examples of vehicles with adjuvant-like activities include water/oil emulsions, oil/water emulsions, microencapsulation, and liposomes (paragraph 15), and in Example II, disclose a vaccine emulsion formulation comprising a mixture of .beta.-glucan-phospholipid conjugate, phosphatidylcholine and vitamin E (paragraph 44).

The teachings of Andersen et al. Chaturvedi et al. Unger et al. and Parikh are directed to the production of vaccines formulations. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art, to combine their respective teachings and to produce cell wall fragments from the H37Rv strain encapsidated in liposomes as a vaccine composition further comprising vitamin E, as instantly claimed, with a reasonable expectation of success, at the time of the instant invention. A person of ordinary skill in the art would have been motivated to include vitamin E as a liposomal pharmaceutical vaccine composition, because Parikh specifically teaches the same.

Response to Arguments:

Applicants disagree with the rejection, repeating substantially the same arguments summarized above. Applicants' arguments have been fully considered, but are not found persuasive. Applicants are directed to the response set forth above. Thus, the rejection is maintained.

Citation of Relevant Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Andersen et al. (U.S. Patent Application Publication No.: 2003/0165525) describe methods of preparing subcellular as well as cell wall and membrane fractions of *M. tuberculosis* H37Rv, that include extraction of cells with surfactants and detergents that include SDS in homogenization buffer and the extraction of cell wall and membrane with Triton X-114 to prepare protein fractions largely devoid of lipoarabinomannan (Example 3A, pp. 15-16).

Conclusion

Claims 20, 28-34, 38-43 and 47-60 are not allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR§1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/
Primary Examiner, Art Unit 1633